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\*Substitute Disclosure Statement Form (PTO-1449)

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| FORM 1449*                       | Docket Number              | Application Number |
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| Q.F.                             | D0136NP/30436.58USU1       | 10/057,288         |
| INFORMATION DISCLOSURE STATEMENT | Applicant                  |                    |
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| FORM 1449*                        | Docket Number              | Application Number |
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FORM 1449

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INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION

(Use several sheets if necessary)

**Docket Number Application Number** D0136NP/30436.58USU1 10/057,288 Applicant

Christian P. Larsen et al.

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Sheet  $\underline{3}$  of  $\underline{5}$ FORM 1449\* **Docket Number Application Number** D0136NP/30436.58USU1 10/057,288 INFORMATION DISCLOSURE STATEMENT Applicant IN AN APPLICATION Christian P. Larsen et al. Group Art Unit Filing Date (Use several sheets if necessary) January 25, 2002

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FORM 1449\*

INFORMATION CLOSURE STATEMENT IN AN APPLICATION

**Application Number** D0136NP/30436.58USU1 10/057,288 **Applicant** 

Christian P. Larsen et al.

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FORM 1449\*

INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION

(Use several sheets if necessary)

**Docket Number Application Number** D0136NP/30436.58USU1 10/057,288

Applicant

Christian P. Larsen et al.

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January 25, 2002

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) L104EA29Y (Figure 15, of the subject application) was provided to researchers at Emory University, subject to use restrictions and confidentiality by agreement, more than one year before the priority date of the subject application, i.e. May 26, 2000, for use in animal studies in the U.S. L104EA29Y (Figure 15 of the subject application) has been the subject of human clinical trials under the direction and control of Bristol-Myers Squibb Company. L104EA29Y was given to investigators who were involved in the clinical trials subject to use restrictions and confidentiality by agreement. L104EA29Y was administered intravenously to human patients in clinical trials. L104EA29Y was first administered intravenously to a human patient as early as November 30, 1998 in Scotland. L104EA29Y was first administered intravenously to a human patient as early as April 24, 1999 in the United States. A letter dated July 9, 1998 including a report, submitted to the U.S. Food and Drug Administration in connection with an Investigational New Drug (IND) application, is enclosed as Exhibit 206. The letter and report are confidential and were provided confidentially, pursuant to 21 C.F.R. §20.111 or §21 C.F.R. §312.130, to the Center for Biologics Evaluation and Research at the U.S. Food and Drug Administration in connection with the Investigational New Drug Application. The enclosed letter and report are redacted versions of what were sent to the U.S. Food and Drug Administration. The report contained the sequence for BMS-224818 (Figure 3 at page 13 of Exhibit 206), which differs from CTLA4lg at two amino acid residues, Leu104-Glu and Ala29-Tyr (Exhibit 206 at page 2). (Exhibit 206) An Investigator Brochure dated January 26, 1999 is enclosed as Exhibit 207. The Investigator Brochure is confidential and was provided to investigators who were involved in the clinical trials and subject to confidentiality by agreement, more than one year before the priority date of the subject application, i.e. May 26, 2000. The enclosed Investigator Brochure is a redacted version of what was sent to investigators. The Investigator Brochure contained a text description and a schematic representation of LEA29Y (Figure 1 at page 6 of Exhibit 207), but not the sequence of L104EA29Y (Figure 15, of the subject application). (Exhibit 207)

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|                  | - Figure 1              |          |                  |       |          |                            |
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| /                | 6,444,792 (Exhibit 216) | 09/03/02 | Gray et al.      |       |          | 01/08/99                   |
| 114              | 5,770,197 (Exhibit 220) | 06/23/98 | Linsley et al.   |       |          | 01/22/93                   |
|                  | 6,132,992 (Exhibit 221) | 10/17/00 | Ledbetter et al. |       |          | 10/05/95                   |
| <u> </u>         | 5,977,318 (Exhibit 222) | 11/02/99 | Linsley et al.   |       |          | 06/07/95                   |
|                  | 5,968,510 (Exhibit 223) | 10/19/99 | Linsley et al.   |       | -        | 10/04/96                   |
|                  | 5,993,800 (Exhibit 224) | 11/30/99 | Linsley et al.   |       |          | 06/06/95                   |
| •                | 5,916,560 (Exhibit 225) | 06/29/99 | Larsen et al.    |       |          | 03/20/97                   |
|                  | 5,958,403 (Exhibit 233) | 09/28/99 | Strom et al.     | †     |          | 07/11/94                   |

| $\neg$ | FC                            | REIGN PATENT | DOCUMENTS |       |          |             |           |
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|        | WO 01/90122 A2 (Exhibit 208)  | 11/29/01     | PCT       |       |          |             |           |
| 1      | WO 01/54732 A1 (Exhibit 209)  | 08/02/01     | PCT       |       |          |             |           |
| 1      | WO 00/23115 (Exhibit 210)     | 04/27/00     | PCT       |       |          |             |           |
| 1      | WO 97/28267 (Exhibit 211)     | 08/07/97     | PCT       |       |          |             |           |
| 1      | WO 96/14865 (Exhibit 212)     | 05/23/96     | PCT       |       |          |             |           |
| 1-     | WO 95/34320 (Exhibit 213)     | 12/21/95     | PCT       |       |          |             |           |
| $\top$ | WO 98/31820 (Exhibit 214)     | 07/23/98     | PCT       |       |          |             |           |
| +      | WO 94/28912 (Exhibit 215)     | 12/22/94     | PCT       |       |          |             |           |
| +      | WO 93/19767 (Exhibit 217)     | 10/14/93     | PCT       |       |          |             |           |
| -t     | WO 94/29436 (Exhibit 218)     | 12/22/94     | PCT       |       |          |             |           |
|        | WO 95/33823 (Exhibit 219)     | 12/14/95     | PCT       |       |          |             | $\supset$ |
| 1      | EP 0 613 944 A2 (Exhibit 226) | 09/07/94     | EPO       |       |          |             |           |
|        | EP 0 682 039 A1 (Exhibit 227) | 11/15/95     | EPO       |       |          |             |           |
| 11a    | WO 93/00431 (Exhibit 228)     | 01/07/93     | PCT       |       |          |             |           |

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| []       | WO 98/56417 (Exhibit 229)   | 12/17/98  | PCT                                  |                                    | Ec                                  | W            | 1/1/              |  |  |
| 14       | WO 95/34320 (Exhibit 230)   | 12/21/95  | PCT                                  | 1                                  | 70                                  | 6            | , <               |  |  |
| /        | WO 01/92337 (Exhibit 231)   | 12/06/01  | PCT                                  |                                    |                                     | Ep           | 103               |  |  |
|          | WO 98/33513 (Exhibit 232)   | 08/06/98  | PCT                                  |                                    |                                     | 160          |                   |  |  |
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| 100                        | WO94/01547 (Exhibit 251) | 01/20/94 | PCT     |       |          |             | _ X |  |  |
|                            | W095/06481 (Exhibit 252) | 03/09/95 | PCT     |       |          |             | Х   |  |  |
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